K062542
510(k) Summary - REVISED

OCT 2 9 2007

Z-Systems AG
Z-Look3 Dental Implant System

ADMINISTRATIVE INFORMATION

Manufacturer Name: Z-Systems AG
Bittertenstrasse 15
CH-4702 Oensingen
Switzerland
Telephone 41 62 3886969
FAX 41 62 3886970

Official Contact: Franz Berghänel

Representative/Consultant: Floyd G. Larson
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, CA 92130
Telephone (858) 792-1235
FAX (858) 792-1236

DEVICE NAME

Classification Names: Implant, Endosseous, Root-Form

Trade/Proprietary Name: Z-Look3 Dental Implant System

Common Name Dental implants

ESTABLISHMENT REGISTRATION NUMBER

Z-Systems AG has submitted an Establishment Registration to FDA. The Establishment Registration number and the owner/operator number for Z-Systems AG are pending.

DEVICE CLASSIFICATION

FDA has classified endosseous dental implants as Class II devices (21 CFR 872.3640 according to revision 69 FR 26307, May 12, 2004). The product code for "Implant, Dental, Root-Form" is DZE. Endosseous dental implants are reviewed by the Dental Devices Branch.

INTENDED USE

Z-Look3 Dental Implants are suitable for all indications of endosseous implants in the upper and lower jaw, for the functional and aesthetic oral rehabilitation of edentulous and partially edentulous patients. The Z-Look3 Dental Implants with modifiable abutments are restored with fixed / cemented crowns and bridges. A special indication of the Z-Look3 Dental Implant System is for patients with metal allergies and chronic illnesses due to metal allergies.

Contraindications for the Z-Look3 Dental Implant Ø 3.25 mm:
- Restoration of posterior teeth in the upper or lower jaw
- Single-tooth restoration of canines and central incisors in the upper jaw

DEVICE DESCRIPTION

The Z-Look3 Dental Implant is a one-piece, self tapping, threaded, root form endosseous dental implant. Z-Look3 Dental Implants are offered in three diameters (3.25 mm, 4.0 mm, 5.0 mm) and four lengths (10 mm, 11.5 mm, 13.0 mm, 14.0 mm).

Material

All Z-Look3 implants are produced from ZrO_2 TZP/TZP-A Bio HIP bioceramics, also referred to as yttria-stabilized tetragonal zirconia polycrystal (Y-TZP), conforming to ISO 13356 *Implants for surgery – Ceramic materials based on Yttria-stabilized tetragonal zirconia (Y-TZP)*. This material has been in use for 20 years in the production of hip joint prostheses. It has a fine grain size and offers the best mechanical properties among structural ceramics.

EQUIVALENCE TO MARKETED DEVICE

Z-Systems AG demonstrated that, for the purposes of FDA's regulation of medical devices, the Z-Look3 Dental Implant System is substantially equivalent in indications and design principles to predicate devices, each of which has been determined by FDA to be substantially equivalent to preamendment devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Z-Systems AG
C/O Mr. Floyd G. Larson
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

OCT 2 9 2007

Re: K062542
Trade/Device Name: Z-Look3 Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: October 8, 2007
Received: October 9, 2007

Dear Mr. Larson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

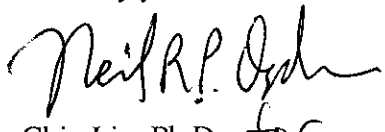
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D. for
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use - REVISED

510(k) Number (if known): K062542

Device Name: Z-Look3 Dental Implant System

Indications for Use:

Z-Look3 Dental Implants are suitable for all indications of endosseous implants in the upper and lower jaw, for the functional and aesthetic oral rehabilitation of edentulous and partially edentulous patients. The Z-Look3 Dental Implants with modifiable abutments are restored with fixed / cemented crowns and bridges. A special indication of the Z-Look3 Dental Implant System is for patients with metal allergies and chronic illnesses due to metal allergies.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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